
STATUTORY INSTRUMENTS

2018 No. 677

The Health Service Products (Provision and Disclosure of Information) Regulations 2018

PART 6

Information about price and availability of health service medicines

Provision of information about English health service medicines which are not available at the reimbursement price

27.—(1) This regulation applies where the Secretary of State has reasonable grounds to suspect that a presentation of English health service medicine is, in a particular month, available for distribution or supply to English NHS chemists at a price which exceeds the listed price.

(2) Where this regulation applies, the Secretary of State may, by request in writing, require any of the following UK producers to provide the information mentioned in paragraph (3) for the relevant presentation—

- (a) a manufacturer of the presentation,
- (b) a person who distributes the presentation (whether by wholesale dealing or otherwise), or
- (c) an importer of the presentation.

(3) The information is—

- (a) the quantity, by relevant pack size, of the presentation which is available for distribution or supply by the producer in England,
- (b) the net price or net prices, or a reasonable estimate of the net price or net prices, at which the producer would offer to distribute or supply those pack sizes in England,
- (c) the quantity, by relevant pack size, of any branded equivalent which is available for distribution or supply by the producer in England, and
- (d) the net price or net prices, or a reasonable estimate of the net price or net prices, at which the producer would offer to distribute or supply those pack sizes in England.

(4) A producer who is given a written request under paragraph (2), must comply with the request within the period of two working days beginning—

- (a) with the day on which producer is given the request, if that day is a working day;
- (b) otherwise, with the first working day after the day on which the notice is given to the producer.

(5) In this regulation—

“branded equivalent”, in relation to a presentation of English health service medicine, means a particular form of medicinal product—

- (a) to which a brand name has been applied that enables the medicine to be identified without reference to the common name, but
- (b) which has the same—

- (i) active ingredient or ingredients,
- (ii) strength,
- (iii) physical form,
- (iv) unit dose (if applicable),
- (v) method of administration (if applicable),
- (vi) freeness (if applicable), and
- (vii) type of packaging,

as the presentation;

“English health service medicine” means a medicinal product used to any extent for the purposes of the health service continued under section 1(1) of the 2006 Act;

“listed price”, in relation to a presentation of English health service medicine, means the price listed for that medicine in Part VIII of the Drug Tariff (England);

“net price”, in relation to a presentation, means the price after the deduction of—

- (a) all discounts and payments, and
- (b) the value of all payments or benefits in kind;

“relevant pack size”—

- (a) in relation to a presentation of English health service medicine which—
 - (i) is a presentation of unbranded generic health service medicine, and
 - (ii) is a liquid or a topical preparation or is in tablet or capsule form,means any pack size which does not exceed the maximum pack size;
- (b) in relation to any other presentation of English health service medicine or a branded equivalent, means any pack size.

(6) For the purposes of this regulation—

- (a) the definition of “presentation” in paragraph 2 of Schedule 1 applies as if any reference to pack size were omitted, and
- (b) for the purpose of determining whether there is price listed in Part VIII of the Drug Tariff (England), any pack size specified in that Part is to be disregarded.